

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Paolo Alberto VERONESI et al.) Group Art Unit:
Application No.:) Examiner:
Filed:) Confirmation No.:
For: NASAL PEPTIDE PHARMACEUTICAL)
FORMULATION)
National Phase of)
International Appln. No. PCT/EP03/006641)
International Filing Date: June 24, 2003)
Earliest Priority Date: July 29, 2002)

FIRST INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98. Applicants request consideration of the documents listed on the accompanying Form PTO-1449. These documents are cited in the English-language International Search Report (copy enclosed).

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of any listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003 and international applications entering the national stage under 35 U.S.C. § 371 after June 30, 2003.

The following document listed on Form PTO-1449 is not in English: IT 1243742B. This patent is in Italian and no English-language counterpart has been located. The English-language ISR serves as a brief statement of relevance. Moreover, it is noted that this patent relates to a pharmaceutical composition based on calcitonin in aqueous solution at pH 3.5-4.5 comprising: a calcitonin, an alkyl ester of p-hydroxybenzoic acid, monobasic tromethamine citrate, povidone and citric acid, in particular proportions, especially adapted for application to the nasal mucosa.

This statement and accompanying Form PTO-1449 and the documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

It is respectfully requested that the Examiner consider this statement and cited documents and that an Examiner-initialed copy of the accompanying Form PTO-1449 be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date December 3, 2004

By: Mary Katherine Baumeister
Mary Katherine Baumeister
Registration No. 26,254

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

10/516613

DT05 Rec'd PCT/PTO 03 DEC 2004

Completing now

Substitute for form 1449A/PTO & 1449B/PTO		Complete shown			
FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT <small>(use as many sheets as necessary)</small>		U.S. Pat. & Tm. Off. Rec'd PCT/PTO U.S. DEC 2000			
Application Number 					
Filing Date 					
First Named Inventor 		Paolo Alberto VERONESI et al.			
Examiner Name 					
Sheet	1	of	1	Attorney Docket Number	019019-009

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

Examiner Signature _____ Date Considered _____

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.